SEP - 8 2000

K002470
Page 1 of 2

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

The submitter of this premarket notification is:

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This summary was prepared on July 24, 2000.

This premarket notification describes several modifications to the M2424A Sonos 5500/4500 system, a diagnostic ultrasound imaging device. It adds of harmonic imaging of tissue to the fetal application to the system and the 21330A transducer. It adds biopsy support to the M2424A system.

The classification names for these devices are:

90 ITX - Diagnostic Ultrasound Transducer
90IYO - Ultrasonic Pulsed Echo Imaging System
90IYN - Ultrasonic Pulsed Doppler Imaging System

The M2424A system and 21330A transducer, with the addition of harmonic imaging of tissue for the fetal application, is substantially equivalent to the predicate device, the Acuson Sequoia system and 4V2 (K973767).

The M2424A, with the addition of biopsy support to the previously cleared abdominal, small parts, transvaginal, and transrectal applications, is substantially equivalent to its predicate device, the Philips P800 sonoDIAGNOST 800 system (K935923).

The modifications to the M2424A system and transducers result in no new technological changes with respect to currently marketed predicate devices.

The M2424A and its transducers have the same indications for use and functionality as its predicate devices.

The M2424A, its transducers, and its predicates allow diagnostic ultrasound imaging and fluid flow analysis of the human body.

The M2424A, its transducers, and its predicates have the same imaging mode capabilities.

The M2424A, its transducers, and its predicates use essentially the same technologies for imaging, Doppler functions and signal processing.

The M2424A, its transducers, and its predicates have acoustic output levels below applicable FDA limits.

The M2424A, its transducers, and its predicates are designed and manufactured tot he same electrical and physical safety standards.

The M2424A transducers and the predicate devices are manufactured with materials with equivalent biosafety for their intended applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2000

Agilent Technologies, Inc.
c/o Ms. Carole Stamp
TÜV Product Service, Inc.
1775 Old Highway 8 NW
Suite 104
New Brighton, MN 55112

Re: K002470
M2424A Ultrasound Imaging System
Regulatory Class: II
21 CFR §892.1550/Procode: 90 IYN
21 CFR §892.1560/Procode: 90 IYO
Dated: August 23, 2000
Received: August 24, 2000

Dear Ms. Stamp:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the 21330A transducer intended for use with the M2424A Ultrasound Imaging System, as described in your premarket notification.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Mr. Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for David A. Seymour

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Agilent Technologies
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Diagnostic Ultrasound Indications for Use Form

510(k) Number: K

Device Name: M2424A Ultrasound Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	MODE OF OPERATION									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (harmonic imaging)
Ophthalmic	NA	P	NA	P	NA	P	P	NA	P	NA
Fetal	NA	P	P	P	P	P	P	P	P	N
Abdominal	NA	P	P	P	P	P	P	P	P	P
Intraoperative (vascular/epicardial)	NA	P	P	P	P	P	P	P	P	NA
Intraoperative Neurological	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pediatric	NA	P	P	P	P	P	P	P	P	P
Small Parts (thyroid, scrotum, prostate & breast)	NA	P	P	P	P	P	P	P	P	P
Neonatal Cephalic	NA	P	P	P	P	P	P	P	P	P
Adult Cephalic	NA	P	P	P	P	P	P	P	P	P
Cardiac (Adult & Pediatric)	NA	P	P	P	P	P	P	P	P	P
Transesophageal	NA	P	P	P	P	P	P	P	P	P
Transrectal	NA	P	P	NA	NA	P	NA	NA	P	NA
Transurethral	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Transvaginal	NA	P	P	NA	P	P	NA	P	P	NA
Intravascular	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Peripheral Vascular	NA	P	P	P	P	P	P	P	P	P
Laparoscopic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Musculo-skeletal Conventional	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Musculo-skeletal Superficial	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Other (specify)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

N = new indication; P = previously cleared by FDA; E = added under Appendix E.

Additional Comments: Combined modes are B+M, B+M+Color, B+PW(CVI), B+PW, B+PW+Color (Triplex). Other: Harmonic imaging of tissue cleared under K980687 & K990339 for: abdominal, pediatric, small parts, neonatal cephalic, adult cephalic, cardiac, transesophageal, peripheral vascular. Biopsy support for abdominal, small parts, transvaginal, & transrectal. Other previously cleared submissions: K934041, K954028, and K971116

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002470

Agilent Technologies
Innovating the HP Way

Diagnostic Ultrasound Indications for Use Form

510(k) Number: _____
Device Name: Transducer 21330A on the M2424A
Intended Use: Diagnostic Ultrasound Imaging or fluid flow analysis of the human body as follows:

	MODE OF OPERATION									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	NA	E	NA	E	E	E	E	NA	E	NA
Fetal	NA	E	E	E	E	E	E	NA	E	N
Abdominal	NA	E	E	E	E	E	E	NA	E	P
Intraoperative	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Intraoperative Neurological	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pediatric	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Small Parts (small organ)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Neonatal Cephalic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Adult Cephalic	NA	E	E	E	E	E	E	NA	E	P
Cardiac	NA	P	P	P	P	P	P	P	P	P
Transesophageal	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Transrectal	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Transvaginal	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Transurethral	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Intravascular	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Peripheral Vascular	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Laparoscopic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Musculo-skeletal Conventional	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Musculo-skeletal Superficial	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Other (specify)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

N = new indication; P = previously cleared by FDA; E = added under Appendix E.
Additional Comments: Combined modes are B+M, B+M+Color, B+PW(CVI), B+PW, B+PW+Color (Triplex). Other: Harmonic imaging of tissue cleared under K980687 & K990339 for: abdominal, adult cephalic, cardiac.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David C. Hegarty
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002470